



Robert Greene Sterne
Edward J. Kessler
Jorge A. Goldstein
David K.S. Cornwell
Robert W. Edmund
Tacy-Gene G. Durkin
Michelle A. Cimbal
Michael B. Ray
Robert E. Solzhi
Eric K. Seife
Michael D. Lee
Steven R. Ludwig
John M. Covert
Linda E. Alcom
Robert C. Millington
Lawrence B. Bugalsky
Donald J. Featherstone
Michael V. Messinger
Justin U. Kim
Timothy J. Shea, Jr.

Patrick E. Garrett
Jeffrey T. Helvey
Hadi L. Kozar
Crystal D. Sayles
Edward W. Nee
Albert S. Judson
Donald R. Barowitz
Peter A. Jaskin
Molly A. McCall
Teresa D. Mader
Jeffrey S. Weaver
Kendrick P. Patterson
Vincent L. Capuano
Albert I. Fasulo II
Bilona Ellison Floyd
W. Russell Swindell
Thomas C. Filla
Brian I. Del Buono
Virgil Lee Beaton
Reginald D. Lucas

Kimberly N. Reddick
Theodore A. Wood
Elizabeth J. Hoanes
Bruce E. Chalker
Joseph S. Ostroff
Frank R. Cottingham
Christine M. Ludler
Rae Lynn Pengasom
Jane Shembrovich
Lawrence J. Carroll
George S. Bardmesser

Senior Counsel
Samuel L. Fox
Kenneth C. Bass III

Registered Patent Agents
Kam R. Markowitz
Andrea J. Kammge

Nancy J. Leith
Joseph M. Conrad III
Ann E. Sommerfeld
Helene C. Carlson
Gabri L. Longworth
Matthew J. Dowd
Aaron I. Schwartz
Annelise G. Uy
Boris A. Matvenilo
Mary B. Tung
Kathryn V. Pei
Brynn L. Shelton
Jason D. Eisenberg
Alicia M. Choi

*Admitted only in Maryland
*Admitted only in Virginia
*Admitted only in Texas

May 20, 2002

WRITER'S DIRECT NUMBER:
(202) 789-5525
INTERNET ADDRESS:
BRIAND@SKGF.COM

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MAY 21 2002

Art Unit 1632

TECH CENTER 1600/2900

Commissioner for Patents
Washington, D.C. 20231

Re: U.S. Continuation Utility Patent Application
Appl. No. 10/024,597; Filed: December 21, 2001
For: **Fusion Proteins Incorporating Lysozyme**
Inventors: Cottingham *et al.*
Our Ref: 0623.0730002/LBB/BJD

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. 12 pages of Form PTO-1449 citing 57 documents;
3. A copy of each of the 57 cited documents; and
4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents
May 20, 2002
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency,
or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Brian J. Del Buono
Attorney for Applicants
Registration No. 42,473

BJD/nef
Enclosures

SKGF_DCI:15267.1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED
MAY 21 2002

In re application of:

Cottingham *et al.*

Appl. No. 10/024,597

Filed: December 21, 2001

For: **Fusion Proteins Incorporating
Lysozyme**

Confirmation No. 2450

Art Unit: 1632

Examiner: *To Be Assigned*

Atty. Docket: 0623.0730002/LBB/BJD

TECH CENTER 1600/2900

Information Disclosure Statement

Commissioner for Patents
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each document is provided.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following concise statement regarding the relevance of the non-English language documents AP1, AN2 and AR1 cited on Form PTO 1449:

Document AP1, WIPO Publication No. WO 92/22644 A1, is in the French language. An unverified English language summary thereof appears on the face page of the publication.

Document AN2, European Patent Office Publication No. 0 590 530, in the name of Behringwerke Aktiengesellschaft, is in the German language. An unverified English language abstract of this publication (from Derwent WPI) is included herewith as Document AT12.

Document AR1, Brignon and Ribadeau-Dumas, *Biochimie* 64:231-235 (1982), is in the French language. An unverified English language summary thereof appears on page 231 of the publication.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Brian J. Del Buono
Attorney for Applicants
Registration No. 42,473

Date: May 20, 2002

1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005-3934
(202) 371-2600



FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 0623.0730002/EKS/BJD	APPLICATION NO. 10/024,597
	APPLICANT Cottingham et al.	
	FILING DATE December 21, 2001	GROUP 1632

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	5,322,775	06/21/1994	Clark et al.	435	69.1	11/22/1991
	AB1	5,366,894	11/22/1994	Clark et al.	435	320.1	11/22/1991
	AC1	5,476,995	12/19/1995	Clark et al.	800	2	08/18/1992
	AD1	5,610,053	03/11/1997	Chung et al.	435	172.3	07/29/1994
	AE1	5,620,923	04/15/1997	Rechsteiner et al.	435	69.7	04/03/1992
	AF1	5,650,503	07/22/1997	Archibald et al.	536	23.5	12/20/1994
	AG1	5,827,690	10/27/1998	Meade et al.	435	69.6	12/20/1993
	AH1	5,861,299	01/19/1999	Archibald et al.	435	240.2	11/17/1994
	AI1	6,211,427 B1	04/03/2001	Cottingham et al.	800	7	10/08/1996
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	EP 0 181 634 A2	05/21/1986	Europe			Yes No
	AM1	WO 88/00239 A1	01/14/1988	WIPO			Yes No
	AN1	WO 90/05188 A1	05/17/1990	WIPO			Yes No
	AO1	WO 92/11358 A1	07/09/1992	WIPO			Yes No
	AP1	WO 92/22644 A1	12/23/1992	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	1	Brignon, G. and Ribadeau-Dumas, B., "A new method for human milk protein separation," <i>Biochimie</i> 64:231-235, Masson (1982).
AS	1	Clark, A.J., et al., "Rescuing Transgene Expression By Co-Integration," <i>Bio/Technol.</i> 10:1450-1454, Nature Publishing Co. (1992).
AT	1	Curtis, R.A., et al., "Protein-Protein and Protein-Salt Interactions in Aqueous Protein Solutions Containing Concentrated Electrolytes," <i>Biotechnol. Bioeng.</i> 57:11-21, John Wiley & Sons, Inc. (January 1998).

EXAMINER	DATE CONSIDERED
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
							Yes
							No
	AL2	WO 93/25567 A1	12/23/1993	WIPO			Yes
							No
	AM2	WO 94/04672 A1	03/03/1994	WIPO			Yes
							No
	AN2	EP 0 590 530 A2	04/06/1994	Europe			Yes
							No
	AO2	WO 95/27782 A1	10/19/1995	WIPO			Yes
							No
	AP2	EP 0 771 874 A2	05/07/1997	Europe			Yes
							No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	2	During, K. "A Tightly Regulated System for Overproduction of Bacteriophage T4 lysozyme in <i>Escherichia coli</i> ," <i>Protein. Expr. Purif.</i> 4:412-416, Academic Press, Inc. (1993).
AS	2	Eipper, B.A., et al., "The Biosynthesis of Neuropeptides: Peptide α -Amidation," <i>Annu. Rev. Neurosci.</i> 15:57-85, Annual Reviews Inc. (1992).
AT	2	Eipper, B.A., et al., "Peptidylglycine α -amidating monooxygenase: A multifunctional protein with catalytic, processing, and routing domains," <i>Protein Sci.</i> 2:489-497, Cambridge University Press (1993).

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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
							Yes No
	AL3	WO 97/42835 A1	11/20/1997	WIPO			Yes No
	AM3	WO 00/29588 A1	05/25/2000	WIPO			Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	3	Fischer, B., et al., "Physiological consequence of expression of soluble and active hen egg white lysozyme in <i>Escherichia coli</i> ," Appl. Microbiol. Biotechnol. 39:537-540, Springer-Verlag (1993).
AS	3	Goldman, A.S., et al., "Immunologic factors in human milk during the first year of lactation," J. Pediatr. 100:563-567, C.V. Mosby Co. (1982).
AT	3	Han, K.-K., et al., "Current Developments in Chemical Cleavage of Proteins," Int. J. Biochem. 15:875-884, Pergamon Press Ltd. (1983).

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	4		Houdebine, L.-M., "Production of pharmaceutical proteins from transgenic animals," J. Biotechnol. 34:269-287, Elsevier Science B.V. (1994).
AS	4		Ibrahimi, I.M., et al., "Determinants for protein translocation across mammalian endoplasmic reticulum. Membrane insertion of truncated and full-length prelysozyme molecules," Eur. J. Biochem. 155:571-576, Springer International (1986).
AT	4		Jacquot, J., et al., "Identification of Different Molecular Forms of Human Airway Lysozyme," Anal. Biochem. 160:227-232, Academic Press, Inc. (1987).

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
	AR	5	Jespersen, L., et al., "Overexpression of the phage lambda lysozyme cloned in <i>Escherichia coli</i> : use of a degenerative mixture of synthetic ribosome binding sites and increase of the protein stability in vivo," <i>Protein Eng.</i> 4:485-492, Oxford University Press (1991).				
	AS	5	Lee, S.H. and de Boer, H.A., "Production of biomedical proteins in the milk of transgenic dairy cows: the state of the art," <i>J. Control. Rel.</i> 29:213-221, Elsevier Science B.V. (1994).				
	AT	5	Lindahl, L., and Vogel, H.J., "Metal-Ion-Dependent Hydrophobic-Interaction Chromatography of α -Lactalbumins," <i>Anal. Biochem.</i> 140:394-402, Academic Press, Inc. (1984).				
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	AL						Yes No
	AM						Yes No
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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
	AR	6	Lollike, K., et al., "Purification of Lysozyme from Human Neutrophils, and Development of an ELISA for Quantification in Cells and Plasma," <i>Leukemia</i> 9:206-209, Stockton Press (1995).				
	AS	6	Lönnerdal, B., et al., "A longitudinal study of the protein, nitrogen, and lactose contents of human milk from Swedish well-nourished mothers," <i>Am. J. Clin. Nutr.</i> 29:1127-1133, American Society of Clinical Nutrition (1976).				
	AT	6	McCreath, G.E., et al., "Preparation and use of ion-exchange chromatographic supports based on perfluoropolymers," <i>J. Chrom. A.</i> 773:73-83, Elsevier Science B.V. (1997).				

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	AL						Yes No
	AM						Yes No
	AN						Yes No
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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	2	McKee, C., et al., "Production of biologically active salmon calcitonin in the milk of transgenic rabbits," <i>Nature Biotechnol.</i> 16:647-651, Nature Publishing Co. (July 1998).
AS	2	Noppe, W., et al., "Simple two-step procedure for the preparation of highly active pure equine milk lysozyme," <i>J. Chrom. A</i> 719:327-331, Elsevier Science B.V. (1996).
AT	2	Okun, M.M., et al., "Truncations of a Secretory Protein Define Minimum Lengths Required for Binding to Signal Recognition Particle and Translocation across the Endoplasmic Reticulum Membrane," <i>J. Biol. Chem.</i> 265:7478-7484, American Society for Biochemistry and Molecular Biology, Inc. (1990).

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	AN						Yes No
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	§	Paleyanda, R.K., et al., "Transgenic pigs produce functional human factor VIII in milk," <i>Nature Biotechnol.</i> 15:971-975, Nature Publishing Co. (1997).
AS	§	Prasad, R.V., et al., "Amino Acid Sequence of Rat α -Lactalbumin: A Unique α -Lactalbumin," <i>Biochemistry</i> 21:1479-1482, American Chemical Society (1982).
AT	§	Pursel, V.G., et al., "Genetic Engineering of Livestock," <i>Science</i> 244:1281-1288, American Association for the Advancement of Science (1989).

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
	AR	2	Pursel, V.G. and Rexroad, C.E. Jr., "Status of Research with Transgenic Farm Animals," <i>J. Anim. Sci.</i> 71:10-19, American Society of Animal Science (1993).				
	AS	2	Ray, M.V.L., et al., "Production of Recombinant Salmon Calcitonin by <i>In Vitro</i> Amidation of an <i>Escherichia coli</i> Produced Precursor Peptide," <i>Bio/Technol.</i> 11:64-70, Nature Publishing Co. (1993).				
	AT	2	Sloane, R.P., et al., "Expression and purification of a recombinant metal-binding T4 lysozyme fusion protein," <i>J. Biotechnol.</i> 49:231-238, Elsevier Science B.V. (1996).				

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>10</u>	Vachier, M.C., et al., "Isolation of hen egg white lysozyme, ovomucoprotein and ovalbumin, using a quaternary ammonium bound to a highly crosslinked agarose matrix," J. Chrom. B. 664:201-210, Elsevier Science B.V. (1995).
AS	<u>10</u>	Van Heeke, G., et al., "Gene Fusions with Human Carbonic Anhydrase II for Efficient Expression and Rapid Single-Step Recovery of Recombinant Proteins: Expression of the <i>Escherichia coli</i> F ₁ -ATPase c Subunit," Prot. Exp. Purif. 4:265-274, Academic Press, Inc. (1993).
AT	<u>10</u>	Vasstrand, E.N. and Jensen, H.B., "Affinity chromatography of human saliva lysozyme and effect of pH and ionic strength on lytic activity," Scand. J. Dental Res. 88:219-228, Munksgaard (1980).

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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
	AR	11	Vilotte, J.-L., et al., "Efficient tissue-specific expression of bovine α -lactalbumin in transgenic mice," <i>Eur. J. Biochem.</i> 186:43-48, Springer International (1989).				
/	AS	11	Winters, M.A., et al., "Protein Purification with Vapor-Phase Carbon Dioxide," <i>Biotechnol. Bioeng.</i> 62:247-258, John Wiley & Sons, Inc. (February 1999).				
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EXAMINER	DATE CONSIDERED
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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 0623.0730002/EKS/BJD	APPLICATION NO. 10/024,597
	APPLICANT Cottingham et al.	
	FILING DATE December 21, 2001	GROUP 1632

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
AR	12	Wright, G., et al., "High Level Expression of Active Human Alpha-1-Antitrypsin in the Milk of Transgenic Sheep," <i>Bio/Technol.</i> 9:830-834, Nature Publishing Co. (1991).					
AS	12	NCBI Entrez, Genbank Accession No. X14008, from Sippel, A.E., National Center for Biotechnology Information (1997).					
AT	12	Unverified English language abstract of EP 0 590 530 A2 (Document AN2), Derwent World Patent Index (Dialog File 351), Derwent WPI Acc. No. 94-111012/14, Derwent Info Ltd. (1997).					

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